

**CENTER FOR VETERINARY MEDICINE
PROGRAM POLICY AND PROCEDURES MANUAL GUIDE 1243.2580**

**OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER**

SUBMISSION IDENTIFICATION SYSTEM

- I. Purpose
- II. General Information
- III. Document Types and Codes
- IV. Submission Codes for NADAs/ANADAs
- V. Submission Codes for INADs/JINADs
- VI. Submission Codes for IFAPs
- VII. Submission Codes for IFAs
- VIII. Submission Codes for GC/VMF/PMF
- IX. Submission Codes for Drug Experience Reports
- X. Document Submission Codes and Review Timeframes

I. PURPOSE

The purpose of this guide is to provide an understanding of the submission identification system and established review times used by the Center for Veterinary Medicine. The submission identification system that is used to track documents is the Submission Tracking and Retrieval System (STARS).

II. GENERAL INFORMATION

The Center identifies every request or submission by a unique Submission Identification code (ID). An understanding of the vocabulary used in this identification system is crucial for full utilization and understanding of the Center's submission processing.

Information submitted to the Center is placed into organized files. Examples include New Animal Drug Applications (NADAs) and Investigational New Animal Drug (INAD) files. A submission ID is a combination of the following

four elements: a one-letter Document Code, a six-digit Document Number, a one-letter Submission Code, and a four-digit Submission Number.

When describing files in this guide, CVM uses the terms “sponsor” and “firm” synonymously.

III. DOCUMENT NAMES AND CODES

Document Name	Code
New Animal Drug Application (NADA)	N
Abbreviated New Animal Drug Application (ANADA)	A
Investigational New Animal Drug File (INAD)	I
Generic Investigational New Animal Drug File (JINAD)	J
Veterinary Master File (VMF)	V
Public Master File (PMF)	P
General Correspondence (GC)	G
Drug Experience Report (DER)	D
Food Additive Petition (FAP)	C
Investigational Food Additive File (IFA)	B

IV. SUBMISSION CODES FOR NADAs/ANADAs

The most common NADA and ANADA submission codes, further defined by classification codes, include the following:

Sub Code	Submission Type Name	Sub Class Code	Submission Classification Name
A	ORIGINAL		
B	CHEMISTRY REPORT	CA	CHEMISTRY ANNUAL REPORT
B	CHEMISTRY REPORT	CB	CHEMISTRY BIENNIAL SUPPLEMENT
C	SUPPLEMENT	CP	CHEMISTRY PRIOR APPROVAL
C	SUPPLEMENT	CI	CHEMISTRY IMMEDIATE CHANGE BEING EFFECTED
C	SUPPLEMENT	CS	CHEMISTRY THIRTY-DAY CHANGE BEING EFFECTED
C	SUPPLEMENT	CC	CHEMISTRY COMPARABILITY PROTOCOL
C	SUPPLEMENT	OT	OTHER; UNCLASSIFIED
E	REACTIVATION OF ORIGINAL		
F	REACTIVATION OF CHEMISTRY REPORT	CA	CHEMISTRY ANNUAL REPORT REACTIVATION
F	REACTIVATION OF CHEMISTRY REPORT	CB	CHEMISTRY BIENNIAL SUPPLEMENT REACTIVATION
G	GENERAL CORRESPONDENCE		
M	AMENDMENT TO ORIGINAL		
Q	AGENCY (CVM) INITIATED ACTION		
R	REACTIVATION OF SUPPLEMENT	CP	CHEMISTRY PRIOR APPROVAL REACTIVATION
R	REACTIVATION OF SUPPLEMENT	CC	CHEMISTRY COMPARABILITY PROTOCOL REACTIVATION
R	REACTIVATION OF SUPPLEMENT	CI	CHEMISTRY IMMEDIATE CHANGE REACTIVATION
R	REACTIVATION OF SUPPLEMENT	CS	CHEMISTRY THIRTY-DAY CHANGE REACTIVATION
R	REACTIVATION OF SUPPLEMENT	OT	OTHER; UNCLASSIFIED
S	AMENDMENT TO A SUPPLEMENT		
T	AMENDMENT TO A REACTIVATED ORIGINAL		
U	AMENDMENT TO REACTIVATION OF SUPPLEMENT		
Y	FIRM'S MEETING MINUTES	PS	PRESUBMISSION CONFERENCE MEETING MINUTES
Y	FIRM'S MEETING MINUTES	OT	OTHER; UNCLASSIFIED
Z	REQUEST FOR MEETING	PS	PRESUBMISSION CONFERENCE
Z	REQUEST FOR MEETING	OT	OTHER; UNCLASSIFIED

Original Application (A) — The first submission of the application. It must include complete information and data that address all applicable sections of 21 CFR 514.

Supplemental Application (C) — A request for a change in the conditions of the present approval.

Chemistry Report (B) — A report of minor changes and stability report or biennial supplement (prior to November 1999).

Reactivation — The Sponsor may reactivate a previously deficient or incomplete original or a supplemental application by responding to all the deficiencies cited in the Center's incomplete letter. The following submission codes are based on the submission they reactivate:

- E** Reactivation of an Original
- R** Reactivation of a Supplement
- F** Reactivation of Chemistry Annual Report or biennial supplement (prior to November 1999).

Amendment (*) — The Sponsor may amend information in any pending application while it is under review by the Center. The following amendment codes are based on the type of submission they amend:

- M** Amendment to an Original
- S** Amendment to a Supplement/Chemistry Annual Report
- T** Amendment to a Reactivated Original
- U** Amendment to a Reactivated Supplement/Chemistry Annual Report

Sponsor's Meeting Request and Agenda (Z) — Request for a meeting between the Sponsor and CVM personnel and submission of a proposed agenda for the meeting.

Sponsor's Meeting Minutes (Y) — A request to file the Sponsor's minutes of a previous meeting in the administrative record.

Agency-Initiated Action (Q) — Used for special CVM-initiated actions, e.g., non-voluntary withdrawal of approval, which are tracked in STARS.

General Correspondence (G) — All other submissions or requests.

V. SUBMISSION CODES FOR INADs/JINADs

The most common INAD/JINAD submission codes, further defined by classification codes, include the following:

Sub Code	Submission Type Name	Sub Class Code	Submission Classification Name
A	INITIAL SUBMISSION		
B	NOTICE OF SHIPMENT		
C	DIAL SUBMISSION CODE		
D	AMENDED AUTHORIZATION		
E	PROTOCOL - NO DATA		
F	PROTOCOL – DATA		
G	GENERAL CORRESPONDENCE		
H	STUDY REVIEW		
J	EMERGENCY/COMPASSIONATE		
M	ESTABLISHMENT INSPECTION REPORT		
O	ORIG AUTHORIZATION		
P	STUDY With SUBSTANTIAL DATA		
Q	AGENCY (CVM) INITIATED ACTION		
R	REQUEST FOR WAIVER OF BIOEQUIVALENCE		
S	FIRM'S SLAUGHTER NOTICE		
T	AMENDMENT TO INAD		
U	USDA SLAUGHTER REPORT		
V	FIRM'S FINAL DISPOSITION		
Y	FIRM'S MEETING MINUTES	PS	PRESUBMISSION CONFERENCE MEETING MINUTES
Y	FIRM'S MEETING MINUTES	OT	OTHER; UNCLASSIFIED
Z	REQUEST FOR MEETING	PS	PRESUBMISSION CONFERENCE
Z	REQUEST FOR MEETING	OT	OTHER; UNCLASSIFIED
	REFUSE TO REVIEW		
	STOP REVIEW		

Initial Submission/Opening of File (A) — First submission requesting establishment of an INAD file. If the original submission request includes a Slaughter Authorization, it should be coded as (O).

Original Slaughter Authorization Request (O) — Request for FDA approval to slaughter and market for consumption edible products derived from animals treated with an investigational drug.

Amended Slaughter Authorization Request (D) — Request for a revision of the conditions of the original slaughter authorization.

Notice of Claimed Investigational Exemption for a New Animal Drug (B) — [Also known as a Notice of Drug Shipment]. Notification to CVM of the shipment or receipt of an investigational drug.

Sponsor's Final Disposition of Experimental Animals (V) — Notification to CVM by the Sponsor of the final disposition of animals.

Emergency or Compassionate Use Request (J) — Request to use an investigational drug in order to save an animal's life and statement of intent to establish an INAD file.

USDA Slaughter Report (U) — Report from USDA of animals slaughtered that received investigational drugs.

Sponsor's Slaughter Notice (S) — Report from the Sponsor of animals slaughtered that received investigational drugs.

Establishment Inspection Report (M) — Official report of an inspection of a sponsor, investigator, or manufacturing site, prepared by FDA.

Request for Waiver of Bioequivalence (R) — Request a waiver for the requirement of conducting an *in vivo* bioequivalence study if the proposed generic product formulation meets certain criteria.

Amendments to INAD (T) — Any amendment to a pending INAD submission.

Submissions Relating to Technical Sections:

Protocol Review with No Data (E) — Request for CVM's comments on a protocol with no supporting data.

Protocol Review with Supporting Data (F) — Request for CVM's evaluation of a protocol with supporting data.

Study Review (H) — Request for CVM's evaluation of data from a study with limited data.

Study Review with Substantial Data (P) — Request for CVM's evaluation of a study with substantial data.

Agency-Initiated Action (Q) — Used for special CVM-initiated actions, e.g., non-voluntary withdrawal of approval, which are tracked in STARS.

Sponsor's Meeting Request and Agenda (Z) — Request for a meeting between the Sponsor and CVM personnel and submission of a proposed agenda for the meeting.

DIAL Submission Code (C) — [Document Inventory And Locator database]. A code, no longer used, from the predecessor of the STARS system. Provided only for historical information.

Sponsor's Meeting Minutes (Y) — A request to file the Sponsor's minutes of a previous meeting in the administrative record.

General Correspondence (G) — All other submissions or requests.

VI. SUBMISSION CODES FOR FOOD ADDITIVE PETITIONS (FAP)

The Division of Animal Feeds, Office of Surveillance and Compliance (OS&C), administratively handles Food Additive Petitions; however, they may request ONADE reviewers to provide technical reviews. Once approved, Food Additive Petitions cannot be supplemented.

FAPs do not use classification codes. Submission codes used for FAPs follow:

Sub Code	Submission Type Name
A	ORIGINAL
C	DIAL SUBMISSION CODE
E	REACTIVATION OF ORIGINAL
G	GENERAL CORRESPONDENCE
M	AMENDMENT TO ORIGINAL
Q	AGENCY (CVM) INITIATED ACTION
T	AMENDMENT TO REACTIVATION

Original Petition (A) — The first submission of the petition. It must include complete information as stated in the regulations.

Reactivation of Original (E) — The petitioner may respond to a previously deficient petition by addressing the deficiencies cited in CVM's incomplete letter.

Amendment — The petitioner may amend the information in any pending petition using the following codes:

(M) Amendment to an Original

(T) Amendment to a Resubmitted Original

Agency-Initiated Action (Q) — Used for special CVM-initiated actions, e.g., non-voluntary withdrawal of approval, which are tracked in STARS.

Dial Submission Code (C) — [Document Inventory And Locator database]. A code, no longer used, from the predecessor of the STARS system. Provided only for historical information.

General Correspondence (G) — All other submissions or requests.

VII. SUBMISSION CODES FOR INVESTIGATIONAL FOOD ADDITIVE (IFA) FILE

The Division of Animal Feeds, OS&C, administratively handles Food Additive Petitions; however, they may request ONADE reviewers to provide technical reviews. These submission codes are classified on the type of information they include as well as the request of the Sponsor. IFA submission codes are as follows:

Sub Code	Submission Classification Name
A	ORIGINAL AUTHORIZATION
B	NOTICE OF SHIPMENT
C	DIAL SUBMISSION CODE
D	AMENDED AUTHORIZATION
E	PROTOCOL – NO DATA
F	PROTOCOL – DATA
G	GENERAL CORRESPONDENCE
M	ESTABLISHMENT INSPECTION REPORT
Q	AGENCY (CVM) INITIATED ACTION
S	PETITIONER'S SLAUGHTER NOTICE
U	USDA SLAUGHTER NOTICE

Initial Submission/Opening of File (A) — First submission requesting establishment of an IFA file.

Amended Slaughter Authorization Request (D) — Request for a revision of the conditions of the original authorization.

Protocol Review with No Data (E) — Request for CVM's comments on a protocol for an FAP-supporting study.

Protocol Review with Supporting Data (F) — Request for CVM's evaluation of a protocol with supporting data.

Notice of Claimed Investigational Exemption for a New Food Additive Petition (B) — Notification to CVM of the shipment or receipt of an investigational food additive (also called a Notice of Shipment of an Investigational Food Additive).

Establishment Inspection Report (M) — Official report of an inspection of an investigator or manufacturing site, prepared by FDA inspectors.

Agency-Initiated Action (Q) — Used for special CVM-initiated actions, which are tracked in STARS.

USDA Slaughter Report (U) — Report from USDA of animals slaughtered that received investigational food additives.

Petitioner's Slaughter Notice (S) — Report from the petitioner of animals slaughtered that received investigational food additives.

Dial Submission Code (C) — [Document Inventory And Locator database]. A code, no longer used, from the predecessor of the STARS system. Provided only for historical information.

General Correspondence (G) — All other submissions or requests.

VIII. SUBMISSION CODES FOR GC/VMF/ PMF

These files are general repositories of information and can contain a variety of different material; the submission codes reflect only the opening submission to the file and subsequent requests. Submission codes for GC/VMF/PMF, further defined by classification codes, follow:

Sub Code	Submission Type Name	Sub Class Code	Submission Classification Name
Y	SPONSOR'S MEETING MINUTES	PS	PRESUBMISSION CONFERENCE MEETING MINUTES
Y	SPONSOR'S MEETING MINUTES	OT	OTHER; UNCLASSIFIED
Z	REQUEST FOR MEETING	PS	PRESUBMISSION CONFERENCE
Z	REQUEST FOR MEETING	OT	OTHER; UNCLASSIFIED
A	ORIGINAL		
C	SUBSEQUENT SUBMISSIONS		
E	PROTOCOL REVIEW- WITH NO DATA		
T	AMENDMENT TO VMF/PMF/GC		
Q	AGENCY INITIATED ACTIONS		
G	GENERAL CORRESPONDENCE		

Original (A) — The initial request that opens a document.

Subsequent Submissions (C) — Any subsequent submissions to the document.

Sponsor's Meeting Request and Agenda (Z) — Request for a meeting between the Sponsor and CVM personnel and submission of a proposed agenda for the meeting.

Sponsor's Meeting Minutes (Y) — A request to file the Sponsor's minutes of a previous meeting in the administrative record.

Protocol Review With No Data (E) — Request for CVM’s comments on a protocol with no supporting data. Not applicable for GC and VMF.

Amendment to VMF/PMF/GC (T) — Any amendment to a pending submission.

Agency Initiated Actions (Q) — Used for special CVM-initiated actions, which are tracked in STARS.

General Correspondence (G) — All other submissions or requests. Not applicable for GC.

IX. SUBMISSION CODES FOR DRUG EXPERIENCE REPORTS

Drug Experience Reports (DERs) are required to be submitted to the DCU at six month intervals beginning with the date of approval and annually thereafter. 21 CFR 510.300 requires special reports for certain promotional and advertising materials, and for adverse drug experiences.

<u>DER</u>	<u>Report</u>
A	Annual DER
S	Semi-Annual DER
L	Special DER
P	Post Approval Monitoring Program (PAMP)

X. DOCUMENT SUBMISSION CODES AND REVIEW TIMEFRAMES

The following table provides the review times associated with each of the submission codes:

Original/Abbreviated New Animal Drug Application

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
A/N	A/NADA	A	Original	180
	A/NADA	B	Notice of Shipment	50
	A/NADA	C	Supplement	180
	A/NADA	E	Reactivation of Original	180
	A/NADA	F	Protocol – No Data	50
	A/NADA	G	General Correspondence	180
	A/NADA	M	Amendment To Original	**
	A/NADA	Q	Agency Initiated Actions	**
	A/NADA	R	Reactivation Of Supplement	180
	A/NADA	S	Amendment To A Supplement	**
	A/NADA	T	Amendment To Reactivation	**
	A/NADA	U	Amendment To Reactivation of Supplement	**
	A/NADA	Y	Sponsor's Meeting Minutes	50
	A/NADA	Z	Request For Meeting	50***

* Submission review timeframes are set from CVM receipt date.

** Amendment review times assumes due date of the amended submission.

** There is no set review time for Q Submission codes. When FDA initiates an action and this action is tracked in the STARS, the due date is set by the individual making the request. The date of memo sent to the document control unit requesting a Q “submission” is used as the correspondence date. This memo will set a due date.

*** Request for meeting review timeframes are set from date of meeting.

Original/Generic Investigational New Animal Drug File

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
I/ J	J/INAD	A	Initial Submission	100
	J/INAD	B	Notice of Shipment	50
	J/INAD	C	Dial Submission Code	N/A
	J/INAD	D	Amended Authorization	100
	J/INAD	E	Protocol - No Data	50
	J/INAD	F	Protocol - Data	100
	J/INAD	G	General Correspondence	100
	J/INAD	H	Study Review	100
	J/INAD	J	Emergency/Compassionate	100
	J/INAD	M	Establishment Inspection Report	45
	J/INAD	O	Original Authorization	100
	J/INAD	P	Study With Substantial Data	180
	J/INAD	Q	Agency Initiated Actions	**
	J/INAD	R	Waiver Of Bioequivalence	50
	J/INAD	S	Sponsor's Slaughter Notice	50
	J/INAD	T	Amendment to Reactivation	**
	J/INAD	U	USDA Slaughter Report	50
	J/INAD	V	Sponsor's Final Disposition	50
	J/INAD	Y	Sponsor's Meeting Minutes	50
	J/INAD	Z	Request For Meeting	50

* Submission review timeframes are set from CVM receipt date.

** There is no set review time for Q Submission codes. When FDA initiates an action and this action is tracked in the STARS, the due date is set by the individual making the request. The date of memo sent to the document control unit requesting a Q "submission" is used as the correspondence date. This memo will set a due date.

** Amendment review times assumes due date of the amended submission.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

Food Additive Petition

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
C	FAP	A	Original	90+90 [♦]
	FAP	C	Dial Submission Code	N/A
	FAP	E	Reactivation Of Original	90+90
	FAP	G	General Correspondence	180
	FAP	M	Amendment To Original	90+90
	FAP	T	Amendment To Reactivation	180

Investigational Food Additive File

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
B	IFA	A	Original Authorization	130
	IFA	B	Notice of Shipment	45
	IFA	C	Dial Submission Code	N/A
	IFA	D	Amended Authorization	130
	IFA	E	Protocol - No Data	45
	IFA	F	Protocol – Data	130
	IFA	G	General Correspondence	90
	IFA	M	Amendment to Original	45
	IFA	Q	Agency Initiated Actions	**
	IFA	S	Sponsor's Slaughter Notice	45
	IFA	U	USDA Slaughter Notice	45

[♦] FAPs have a 90-day review time, which by letter can be extended an additional 90 days.

* Submission review timeframes are set from CVM receipt date.

** There is no set review time for Q Submission codes. When FDA initiates an action and this action is tracked in the STARS, the due date is set by the individual making the request. The date of memo sent to the document control unit requesting a Q “submission” is used as the correspondence date. This memo will set a due date.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

General Correspondence

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
G	GC	A	Original	180
	GC	C	Supplement	180
	GC	Y	Sponsor's Meeting Minutes	50
	GC	Z	Request For Meeting	50
	GC	Q	Agency Initiated Actions	**
	GC	T	Amendment to a GC	**

Veterinary Master Files

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
V	VMF	A	Original	180
	VMF	C	Update	180
	VMF	Y	Sponsor's Meeting Minutes	50
	VMF	Z	Request For Meeting	50
	VMF	G	General Correspondence	90
	VMF	Q	Agency Initiated Actions	**
	VMF	T	Amendment to a VMF	**

* Submission review timeframes are set from CVM receipt date.

** There is no set review time for Q Submission codes. When FDA initiates an action and this action is tracked in the STARS, the due date is set by the individual making the request. The date of memo sent to the document control unit requesting a Q "submission" is used as the correspondence date. This memo will set a due date.

** Amendment review times assumes due date of the amended submission.

Public Master Files

Doc Code	Document Abbreviation	Submission Code	Submission Type Name	CVM* Review Time
P	PMF	A	Original	180
	PMF	C	Update	180
	PMF	Y	Sponsor's Meeting Minutes	50
	PMF	Z	Request For Meeting	50
	PMF	E	Protocol Review	50
	PMF	G	General Correspondence	180

* Submission review timeframes are set from CVM receipt date.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001